K043189

FEB - 9 2005

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part pf the Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions To 21CFR.Part 807, Subpart E, Section 807.92 Content and Format of a 510 (k) Summary.

1) **Submitted By:**

3G Ultrasound Corporation
200 Williams Drive
Ramsey,NJ 07446

Contact Person:
Raul Gutierrez

Phone:(201) 280-4419
Fax: (201) 825-1165

Date Prepared:
September 03, 2004

2) **Proprietary Name:**
Sonalis Ultrasound System

CommonIUsual Name:
Diagnostic Ultrasound with Accessories

Classification Name:
21 CFR892.1560
Ultrasonic Pulsed Echo Imaging System # 892.1560 Product Code 90-IYO
Diagnostic Ultrasound Transducer# 892.1570 Product Code 90-ITX

3) **Substantially Equivalent Devices**

3G Ultrasound Corporation believes that the Sonalis Platform System and transducers are substantially equivalent to the currently marketed Sonada ultrasound System and transducers cleared in K993092.

4) **Device Description**

The Sonalis System is a general purpose ,mobile ,software controlled ,diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation.

The device consists of two parts: the system console and the transducer. The console contains the user interface, a display, system electronics and optional peripherals (printers).

The removable transducers are connected to the system using standard technology. The Sonalis system uses standard transducer technology and supports linear and curved linear arrays.

The Sonalis system gives the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

The Sonalis Platform system has been designed to meet the following standards:

- UL 2601-1 Safety Requirements for Medical Equipment
- CSA C22.2 No 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD 2 Standard for Real-Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment.
- AIUM/NEMA UD 3 Standard for Real-Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment.
- IEC 1157 Declaration of Acoustic Power
- 1EC60601-1-2
- 1EC60601-2-37

4) Intend Use

The Sonalis system and transducers are intended for diagnostic ultrasound imaging of the human body. The clinical application is trans-rectal imaging.

Typical examinations using the Sonalis Platform system

- Prostate and rectal wall studies.

5) Technical Characteristic

This device operates identically to the predicate device in that the piezoelectrical material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D images.

6) Conclusion

The Sonalis Platform ultrasound system and transducers are substantially equivalent in safety and effectiveness to the Sonada system and transducers.

- Both systems are intended for diagnostic ultrasound imaging.

- Both Systems are essentially the same technologies for imaging and signal processing.

    - Both systems have acoustic output levels below the applicable FDA limits.
    - Both systems are manufactured of materials with materials that have been evaluated and found to be safe for its application.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 2005

3G Ultrasound, Inc.
% Paul Schneider, Ph.D.
Official Correspondent
Schneider Associates, Inc.
12672 Coral Lakes Drive
BOYNTON BEACH FL 33437

Re: K043189
Trade Name: SONALIS Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: January 27, 2005
Received: January 28, 2005

Dear Dr. Schneider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONALIS Ultrasound System, as described in your premarket notification:

Transducer Model Number

SONO 2001
SONO 2002

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) *		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N								
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

SONALIS ULTRASOUND SYSTEM

* Thyroid, Testes, Breast

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043189

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Pediatnc										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N								
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

SONO 2001 Transducer

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ...ological Devices

...mber K043189

Diagnostic Ultrasound Indications for Use Form

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Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

SONO 2002 Transducer Thyroid, Testes, Breast

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043189

Prescription Use (Per 21 CFR 801.109)